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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,889	11/14/2003	Benjamin Levinson	WELLSP 3.0-003	1106

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EXAMINER
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FEDOWITZ, MATTHEW L

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/713,889	LEVINSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Matthew L. Fedowitz	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/17/04 &amp; 11/14/03</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

✓

### **DETAILED ACTION**

Claims 1-37 are pending in this action.

#### ***Claim Objections***

Claim 17 is objected to because the claim uses the term "pharma" when it should properly use the term "pharmaceutically." Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4, 6-31 and 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-31 and 33-37 are indefinite because they are drawn to or depend from tin mesoporphyrin compounds complexed with a second agent such as an amino acid without showing how the tin mesoporphyrin is complexed to the amino acid. The applicant has provided no chemical structures showing how the two components are complexed. As a result, there are a multitude of complexes that the tin mesoporphyrins can form with the amino acids because the amino acids have differing chemical structures that can complex to differing locations on the tin mesoporphyrin. Further, since the claims are drawn to complexing the tin mesoporphyrin with "a" second agent, the singular second agent can potentially complex on any location of the tin

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mesoporphyrin. Therefore, these claims and those depending therefrom will be interpreted as any amino acid complex with a tin mesoporphyrin.

Claims 4 and 14 are indefinite because they depend from a claim 2 that is drawn to the complexation of the mesoporphyrin compound with “an amino acid” and the states that the amino acid is selected from combinations of the amino acids. The applicant essentially speaks to using a single amino acid in the base claim and then intends to use combinations of amino acids in claims 4 and 14. It is universally accepted that when one uses a combination of some item then there must be more than one item. As a result, these claims are indefinite. Claim 14 is also indefinite because it refers to the method of claim 2 and claim 2 is not a method claim; therefore, these claims will be interpreted as referring to claim 12.

Claim 21 is indefinite because the claim is drawn to using a “tin mesoporphyrin intermediate” with out defining how the mesoporphyrin is an intermediate from claim 11. Claim 11 is not drawn to creating an intermediate but is drawn to preparing a tin mesoporphyrin compound. Claim 21 is also indefinite because the claim states that the formate salt must be dried to obtain a tin mesoporphyrin formate then subjecting the mesoporphyrin IX formate to the rest of the method. The claim language leads one to believe that tin mesoporphyrin formate and mesoporphyrin IX formate are different compounds in the claim and, as a result, renders this claim indefinite.

Claim 23 is indefinite because of the use of the term “hydrogenation catalyst.” This term is not defined in the specification and is indefinite as to its meaning because no direction is given to determine what a “hydrogenation catalyst” is.

Claim 31 is indefinite because it refers to the method of claim 30. Claim 30 is not a method claim, as it is a composition claim. Therefore this claim is indefinite to that which it is referring.

Claims 24-30 are also rejected as depending from a rejected base claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-20, 22, 32-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson (US 2003/0100752 A1) and Niedballa *et al.* (US 5,275,801).

Claims 1-10 are drawn to a water soluble tin mesoporphyrin compound complexed with a second agent that can be an amino acid such as arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine and tyrosine; where the compound is in liquid or solid form and in combination with a pharmaceutically acceptable carrier. Further, the pharmaceutical formulation contains between 0.1 and 50 mg of tin mesoporphyrin.

Claims 11-20 are drawn to a method of preparing a water soluble complex of tin mesoporphyrin comprising mixing a tin mesoporphyrin compound in solution with an amino acid; where the solution is basic and comprises an aqueous solution of sodium hydroxide; where the amino acid is selected from arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine and tyrosine and an amino acid content is 1:2 with the mesoporphyrin compound;

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where the mesoporphyrin to basic solution content is at least 1:3; further, the formulation is isolated by filtering the formulation solution and then vacuum drying the solid; still further, where the mesoporphyrin compound includes a mesoporphyrin halide such as mesoporphyrin dichloride.

Claim 22 is directed to a pharmaceutical formulation including a tin mesoporphyrin compound mixed with a pharmaceutically acceptable carrier.

As relating to claim 1-10 and 22, Robinson teaches a tin mesoporphyrin compound complexed with a second agent (see table 1, claim 2 and paragraph 189); where the second agent is an amino acid (see claim 2 p. 48); where the compound is in liquid or solid form or a pharmaceutical carrier (see paragraph 189-191); where the amino acids are of a particular form (see paragraphs 186 and 200) and where the formulation can be optimized to contain between 0.1 and 50 mg of the according methods known in the art (see paragraph 193).

Robinson does not teach the compound in the same format as the applicant does. However, those skilled in the art would be motivated to combine the teachings in the manner that the applicant has because Robinson states the compounds taught contain various and ranging substituents that can be substituted on the ring (see paragraph 197).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings above to obtain the compound as claimed in the instant application. All of the moieties, which are substituted in the instant application, are taught in the art, and the locations of substitution are correlative with the locations of substitution in the art. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar

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properties; therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new porphyrin compounds. See *In re Payne*, 203 USPQ 245 (CCPA 1979).

As relating to claims 11-20, Niedballa *et al.* teach a method of producing the water-soluble complex (see column 13 lines 34-68 through column 14 lines 1-12); where the solution is basic (see column 14 lines 13-16); where the solution is that of sodium hydroxide (see column 14 lines 3-5); where the amino acid is selected from a specific form (see column 14 lines 10-11); where the method can be optimized to contain specific amino acid and basic solution to tin meso porphyrin (see column 14 lines 32-39); where the method will result in a solid or pharmaceutically acceptable liquid (see column 14 lines 56-68 through column 15 lines 1-15); where the method includes vacuum drying (see column 14 lines 16-17) and where the mesoporphyrin includes a halide such as dichloride (see column 10 line 66 and column 13 lines 62).

Niedballa *et al.* does not teach the methods in the same format as the applicant does. However, those skilled in the art would be motivated to claim the teachings in the manner that the applicant by making insignificant changes because Niedballa *et al.* provides all of the steps required for such methods (see column 13 lines 34-68 through column 14 lines 1-12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the methods taught in the prior art by making insignificant changes to the teachings above to obtain the methods as claimed in the instant application. One of ordinary skill in the art would be motivated to claim the methods taught by Niedballa *et al.* with insignificant changes in searching for new methods to produce mesoporphyrin complexed compounds.

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B. Claims 32-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson (US 2003/0100752 A1).

Claims 32-35 and 37 are directed to a method of treating a human by administering a pharmaceutically effective amount of a mesoporphyrin compound; where the compound is complexed to a second agent such as an amino acid selected from arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine and tyrosine; and where the treatment is for psoriasis.

Robinson teaches a method of treating with a water-soluble mesoporphyrin compound complexed with a second agent being an amino acid selected from a specific group (see claims 2-15, claims 17-30, claims 32-45, claims 47-60, claims 62-75, claims 77-90, claims 92-105 and claims 107-120) and where the condition is psoriasis (see paragraph 211).

Robinson does not teach the methods in the exact format as the applicant does. However, those skilled in the art would be motivated to combine the teachings in the manner that the applicant has because Robinson provides numerous methods directed toward using the compounds in a therapeutic manner (see claims 2-15, claims 17-30, claims 32-45, claims 47-60, claims 62-75, claims 77-90, claims 92-105 and claims 107-120).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the methods taught in the prior art by making insignificant changes to the teachings above to obtain the methods as claimed in the instant application. One of ordinary skill in the art would be motivated to claim the methods taught by Robinson with insignificant changes to in searching for new methods to use mesoporphyrin complexed compounds in a therapeutic manner.



***Conclusion***

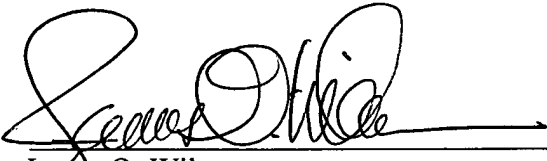
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Matthew L. Fedowitz, Pharm.D., J.D.  
November 9, 2004



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James O. Wilson  
Supervisory Patent Examiner  
Art Unit 1623